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09/038,894	03/11/1998	ROLAND STOUGHTON	UCSD-117	8909
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			MELLER, MICHAEL V	
SUITE 304 MCLEAN, VA	A 22102		ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 09/038.894 STOUGHTON ET AL. Office Action Summary Examiner Art Unit Michael V. Meller 1655 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 16 August 2010. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 10.12.13.16.17.32.33.36 and 38 is/are pending in the application. 4a) Of the above claim(s) 16.17.33.36 and 38 is/are withdrawn from consideration. Claim(s) is/are allowed. 6) Claim(s) 10. 12. 13. 32 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/95/68)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Election/Restrictions

The election of species of record is maintained for the reasons of record.

Applicant elected trauma as the disease/condition, futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-quanidinobenzoate dimethanesulfonate-see claims 18 and 41) as the protease inhibitor (activation lowering therapy) and free radical production as the cell activation assessment method. Thus, claims 16, 17, 33, 36, 38 are withdrawn from further consideration as being drawn to non-elected inventions.

Applicant argues that claims 17, 33 and 38 should not be withdrawn from consideration but it is clear that these claims were subjected to an election of species requirement as noted above. Since applicant elected trauma as the disease/condition, futhan (nafamostate mesilate) as the activation lowering therapy (protease inhibitor) and free radical production as the cell activation assessment method, claims 17, 33 and 38 are withdrawn since they claim non-elected subject matter since the disease/condition elected was trauma which is not in claim 17 and since futhan was elected as the activation lowering therapy then claims 33 and 38 are withdrawn from consideration

since they do not include futhan. Further, claims 16 and 36 are withdrawn since they are drawn to non-elected protease inhibitors.

Thus, claims 16, 17, 33, 36, 38 are withdrawn from further consideration by the examiner as being drawn to non-elected subject matter. This requirement has already been made FINAL.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2 Claims 10, 12, 13, 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed. had possession of the claimed invention.

The claims are drawn to a method of treating symptoms associated with a disease or condition using 6-amidino-2-naphthyl p-quanidinobenzoate

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dimethanesulfonate or a pharmaceutically acceptable salt, acid, ester and other

derivatives thereof.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to "derivatives thereof". The specification gives no evidence as to what "derivatives thereof" means or what it is. Thus, the claims lack written description. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed "derivatives thereof".

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or

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identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only 6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate or a pharmaceutically acceptable salt, acid, ester but not the full breadth of the claims (derivative thereof) meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Further, there is no support in the specification for "repeating the steps of measuring, determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition" in claims 1 and 32. Nowhere in the specification can such support be found and applicant has not pointed the examiner to such support as the applicant must do.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10, 12, 13, 32 are rejected under 35 U.S.C. 103 as being obvious over Rabkin et al. (US 5917013) in view of Groutas (US 5550139) and further in view of JP 409040579.

Rabkin teaches that free radical production associated with oxidative stress is measured using assays such as colormetric assays, see col. 9, lines 40-50. Thus, Rabkin teaches to assess the damage of a disease(s)/condition(s) such as inflammatory disorders such as tissue trauma (as evidenced by Groutas, since Groutas teaches that inflammation is associated with tissue trauma) by assessing the free radical production as taught by Radkin (column 9, lines 40-50). Note also that Rabkin teaches that his

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invention could be administered to someone who has inflammatory disorders, see column 2, lines 40-60. Thus, once inflammation was detected, then treatment would be administered which would mean that the inflammation was elevated which is why it was detected

Rabkin does not teach to use a protease inhibitor such as futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) as the treatment of the trauma once it is determined that treatment is needed for the trauma.

Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that a serine protease such as alpha-1-proteinase inhibitor is administered to reduce inflammation, see column 1, lines 1-45. Thus, as with the teachings of Adams as noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl pguanidinobenzoate dimethanesulfonate) is well known to be used to treat inflammation,
specifically inflammatory bowel disease, see abstract. It establishes that one of ordinary
skill in the art would have known at the time the invention was made that futhan
(nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate
dimethanesulfonate) was known to treat inflammation.

Thus, it would have been obvious to use a protease inhibitor such as the elected futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-quanidinobenzoate

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dimethanesulfonate) of Groutas and JP as the treatment in Rabkin when inflammation was detected since Groutas makes it clear that inflammation is associated with tissue trauma and thus it would be clearly obvious to treat trauma (as elected) with a compound which is known to treat inflammation effectively, in fact JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) is known to treat IBS (Irritable bowel syndrome) effectively.

It further would have been obvious to repeat the steps of measuring, determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition since the method already as explained above already goes through these steps and to repeat them can only improve the treating of symptoms associated with a disease or condition since by repeating the steps one can then more effectively treat the patient since the measuring is redone and the determining can be re-evaluated for effective treatment of the patient.

Applicant argues in their response filed 8/16/2010 that allegedly neither Rabkin, nor Groutas nor JP nor any other reference of record, alone or in combination, teach or suggest the present invention as recited in the pending claims. For example, Applicants argue, Rabkin does not teach or suggest a method which, among other things, administers activation lowering therapy comprising 6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate or a pharmaceutically acceptable salt, acid,

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ester and other derivatives thereof, prior to commencing treatment for the disease or condition if the level of cell activation is elevated.

While this is noted, it is also noted that Rabkin does not have to teach each and every element in the claims. The examiner has already noted this in his rejection and the reasons for using 6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate are clearly on the record.

3. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, applicants argue that allegedly Rabkin does not allegedly disclose repeating the steps of measuring, determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition. Rabkin, at best discloses measuring free radical production using conventional assays. Rabkin simply does not teach such recited and claimed steps, as admitted by the office Action.

This has been addressed above. It further would have been obvious to repeat the steps of measuring, determining and administering activation lowering therapy and

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administering treatment, as needed to ease the symptoms associated with the disease or condition since the method already as explained above already goes through these steps and to repeat them can only improve the treating of symptoms associated with a disease or condition since by repeating the steps one can then more effectively treat the patient since the measuring is redone and the determining can be re-evaluated for effective treatment of the patient.

Furthermore, applicants argue that allegedly Groutas also does not teach such recited steps which are not taught in Rabkin. For example, applicants argue, Groutas does not teach or suggest a method which, among other things, tests cell activation of white blood cells by assays that measure one or more of the level of free radical production, pseudopod formation, adhesion molecule expression and degranulation. administers activation lowering therapy comprising 6-amidino-2-naphthyl pquanidinobenzoate dimethanesulfonate or a pharmaceutically acceptable salt, acid. ester and other derivatives thereof, prior to commencing treatment for the disease or condition if the level of cell activation is elevated, and repeating the steps of measuring, determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition. At best, Groutas allows for a patient to "experience" inflammation, which is completely different from the positively recited step of medical testing for specific physiological conditions. Thus, Groutas does not fairly disclose at least such step so it cannot cure the defects of Rahkin

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Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that a serine protease such as alpha-1-proteinase inhibitor is administered to reduce inflammation, see column 1, lines 1-45. Thus, as with the teachings of Adams as noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

One again, since this is a 35 USC 103 rejection, one reference does not have to teach all of the claimed elements.

Furthermore, applicants argue that allegedly JP cannot cure the deficiencies of Groutas because allegedly JP likewise does not teach or suggest a method which, among other things, tests cell activation of white blood cells by assays that measure one or more of the level of free radical production, pseudopod formation, adhesion molecule expression and degranulation. At best, JP teaches use of futhan in inflammation. It should be noted that inflammation and trauma are mutually exclusive and one does not necessarily involve the other. Thus, the combination of Rabkin, Groutas and JP does not fairly disclose at least such step so it cannot rightfully anticipate or obviate the present invention.

JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl pguanidinobenzoate dimethanesulfonate) is well known to be used to treat inflammation,
specifically inflammatory bowel disease, see abstract. It establishes that one of ordinary
skill in the art would have known at the time the invention was made that futhan

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(nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) was known to treat inflammation. One again, since this is a 35 USC 103 rejection, one reference does not have to teach all of the claimed elements.

Applicant argues that at best, JP teaches use of futhan in inflammation. It should be noted that inflammation and trauma are mutually exclusive and one does not necessarily involve the other. While this is noted, all of the references teach inflammation, thus they do have a common use.

Claims 10, 12, 13, 32 are rejected under 35 U.S.C. 103 as being obvious over WO 92/15707 in view of Groutas (US 5550139) and further in view of JP 409040579.

WO teaches that free radical production is assayed by using immunoassay methods, see abstract, page 20, line 15-page 21, line 10. WO uses its compositions to treat (therapy) of inflammatory diseases, see abstract.

WO states that not only may this permit appropriate actions to avoid the pathogenic potential of these antibodies, but the detection serves in itself as a sensitive measure of ongoing oxidative damage. As noted in the abstract, the immunoassay

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methods are used to diagnose inflammatory diseases as well as monitoring of the progress or therapy of such diseases or conditions. Thus, once inflammation was detected, then treatment would be administered which would mean that the inflammation was elevated which is why it was detected.

WO does not teach to use a protease inhibitor such as futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) as the treatment of the trauma once it is determined that treatment is needed for the trauma.

Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that a serine protease such as alpha-1-proteinase inhibitor is administered to reduce inflammation, see column 1, lines 1-45. Thus, as with the teachings of Adams as noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl pguanidinobenzoate dimethanesulfonate) is well known to be used to treat inflammation,
specifically inflammatory bowel disease, see abstract. It establishes that one of ordinary
skill in the art would have known at the time the invention was made that futhan
(nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate
dimethanesulfonate) was known to treat inflammation.

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Thus, it would have been obvious to use a protease inhibitor such as the elected futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) of Groutas and JP as the treatment in WO when inflammation was detected since Groutas makes it clear that inflammation is associated with tissue trauma and thus it would be clearly obvious to treat trauma (as elected) with a compound which is known to treat inflammation effectively, in fact JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) is known to treat IBS (irratible bowel syndrome) effectively.

It further would have been obvious to repeat the steps of measuring, determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition since the method already as explained above already goes through these steps and to repeat them can only improve the treating of symptoms associated with a disease or condition since by repeating the steps one can then more effectively treat the patient since the measuring is redone and the determining can be re-evaluated for effective treatment of the patient.

Applicants argue that neither WO, nor Groutas nor JP nor any other reference of record, alone or in combination, teach or suggest the present invention as recited in the pending claims. For example, applicants argue, WO does not teach or suggest a method which, among other things, administers activation lowering therapy comprising 6-amidino-2-naphthyl p-quanidinobenzoate dimethanesulfonate or a pharmaceutically

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acceptable salt, acid, ester and other derivatives thereof, prior to commencing treatment for the disease or condition if the level of cell activation is elevated.

While this is noted, it is also noted that WO does not have to teach each and every element in the claims. The examiner has already noted this in his rejection and the reasons for using 6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate are clearly on the record.

4. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, applicants argue, WO does not disclose repeating the steps of measuring, determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition.

WO, at best discloses measuring free radical production using conventional assays.

WO simply does not teach such recited and claimed steps, as admitted by the office Action.

It further would have been obvious to repeat the steps of measuring, determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition since the method

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already as explained above already goes through these steps and to repeat them can only improve the treating of symptoms associated with a disease or condition since by repeating the steps one can then more effectively treat the patient since the measuring is redone and the determining can be re-evaluated for effective treatment of the patient.

Furthermore, applicants argue, Groutas also does not allegedly teach such recited steps which are not taught in Rabkin. For example, applicants argue, Groutas does not teach or suggest a method which, among other things, tests cell activation of white blood cells by assays that measure one or more of the level of free radical production, pseudopod formation, adhesion molecule expression and degranulation, administers activation lowering therapy comprising 6-amidino-2-naphthyl pquanidinobenzoate dimethanesulfonate or a pharmaceutically acceptable salt, acid. ester and other derivatives thereof, prior to commencing treatment for the disease or condition if the level of cell activation is elevated, and repeating the steps of measuring. determining and administering activation lowering therapy and administering treatment, as needed to ease the symptoms associated with the disease or condition. At best, Groutas allows for a patient to "experience" inflammation, which is completely different from the positively recited step of medical testing for specific physiological conditions. Thus, applicants argue, Groutas does not fairly disclose at least such step so it cannot cure the defects of WO.

Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that a serine protease such as alpha-1-proteinase inhibitor is administered to

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reduce inflammation, see column 1, lines 1-45. Thus, as with the teachings of Adams as noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

While this is noted, it is also noted that Groutas does not have to teach each and every element in the claims. The examiner has already noted this in his rejection and the reasons for using 6-amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate and the steps of the method are clearly on the record.

5. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, applicants argue, that JP allegedly cannot sure the deficiencies of Groutas because JP likewise does not teach or suggest a method which, among other things, tests cell activation of white blood cells by assays that measure one or more of the level of free radical production, pseudopod formation, adhesion molecule expression and degranulation. At best, applicants argue, that JP teaches use of futhan in inflammation. It should be noted that inflammation and trauma are mutually exclusive and one does not necessarily involve the other. Thus, the combination of WO, Groutas

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and JP does not fairly disclose at least such step so it cannot rightfully anticipate or obviate the present invention and the rejection should be withdrawn.

Once again, JP does not have to teach each and every element in the claims. The examiner has already noted this in his rejection and the reasons for testing cell activation of white blood cells by assays that measure one or more of the level of free radical production, pseudopod formation, adhesion molecule expression and degranulation are clearly on the record.

6. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/

Primary Examiner, Art Unit 1655